Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D0644326	03/11/2021
Name of Provider or Supplier	**Street Address, City, State**	
Colorado Dept Of Public Health & Environment	8100 Lowry Blvd, Denver, CO	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on personnel competency records reviewed and staff interview, the laboratory failed to ensure technical supervisors (TS) and general supervisors (GS) competency assessment included specific position responsibilities listed in Subpart M. Findings include: 1. Personnel competency records for 2019 and 2020 failed to include documentation of evaluations of specific TS and GS responsibilities besides duties related to patient testing and/or report of patient test results for 12 of 12 TS and for 6 of 6 GS. 2. In an interview conducted on 03/08/2020 at approximately 2:30 P.M. the quality assurance manager confirmed that competency assessments for TS and GS failed to include specific position responsibilities.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and

	indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on test requisition reviewed and staff interview, the laboratory failed to ensure the test requisition solicits the time of specimen collection. Findings include: 1. Laboratory test requisitions for microbiology, serology and molecular testing failed to have a space for recording the time of specimen collection. 7 out of 10 test requisitions reviewed failed to include the time of specimen collection. 2. In an interview conducted on 03/09/2020 at approximately 4:00 P.M. the accessioning department supervisor confirmed the laboratory did not always collect the time of specimen collection.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on serology quality control records reviewed and staff interview, the laboratory failed to ensure statistical parameters for control materials were established over time through concurrent testing of control materials. Findings include: 1. Laboratory lacked documentation to demonstrate the establishment of its own statistically-based quality controls limits for syphilis and HIV ran on the Abbot Architect. 2. Reviewed of the Abbot Architect package insert for syphilis controls states "each laboratory should establish its own concentration target and ranges for new control lots". The Abbot Architect package insert for HIV controls states "using its own standard statistical quality control methods, each laboratory should establish its own S/CO range for each control". 3. In an interview conducted on 03/11/2020 at approximately 1:30 P.M. the serology technical supervisor confirmed the laboratory did not establish its own quality controls ranges for syphilis and HIV ran on the Abbot Architect. Instead they were using the ranges provided by the manufacturer. 4. The laboratory tested approximately 500 samples yearly for syphilis and HIV respectively.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the

	manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the microbiology quality control documents for in-house media, and an interview with the microbiology technical supervisor 2, the laboratory failed to document all quality control steps for the microbiology media made by the laboratory during 2020. Findings: 1. A review of the microbiology quality control spreadsheet for media prepared by the laboratory, revealed the laboratory failed to document all observations and measurements for the microbiology media during 2020. 2. An interview with the microbiology technical supervisor 2, on March 9, 2020, at approximately 11:30 AM, confirmed the laboratory failed to document all control activities for the microbiology media made by the laboratory.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a record review and an interview with the microbiology program manager, the laboratory failed to have a system in place to document the comparison of molecular testing for Sars-Cov-2 performed on the ABI 7500 Dx Fast and the Quant Studio 5 reverse transcription polymerase chain reaction (RT-PCR) instrumentation at least twice a year since January 2021. Findings: 1. A record review of the laboratory's procedure manual, revealed the laboratory failed to have a system in place to evaluate 6 out of 6 ABI 7500 Dx Fast and 4 out of 4 QuantStudio 5 RT-PCR instrumentation and methodologies used to test patient samples for Sars-Cov-2 at least twice a year since January 2021. 2. An interview with the microbiology program manager, on March 9, 2020, at approximately 4:30 PM, confirmed the laboratory failed to have a system in place to evaluate the performance of different test systems for the Sars-Cov-2 tests.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on a record review and an interview with the microbiology technical supervisor 3, the laboratory failed to document the dates, times, identity of testing personnel, and

	each step of bacteriology culture isolation and identification from 20 out of 20 culture specimens received August through December 2020. Findings: 1. A record review of the Clinical Bioterrorism Worksheets from August through December 2020, revealed the worksheets failed to include each step of media inoculation and identification for patient bacteriology samples received for testing. 2. An interview with the microbiology technical supervisor 3, on March 9, 2020, at approximately 10:30 AM, confirmed the laboratory failed to document each step in bacteriology culture inoculation and isolation on the worksheets.